K110335

MAY 19 2011

5. 510(k) Summary

K110335

510k Summary

Device Name: Ceramic Brackets

Submitter's Name, address, telephone number, contact person, and date the summary was prepared:

Submitter's Name: Ortho Organizers Inc.

Submitter's Address: 1822 Aston Ave. Carlsbad, CA 92008

Submitter's Telephone: 760-448-8600

760-448-8613 fax

Submitter's Contact: Foster Boop, Director of Regulatory Affairs and Quality Assurance

Email: Foster.Boop@OrthoOrganizers.com

Ph. 760-448-8600 ext 146

Date 510(K) Summary Prepared: January 31, 2011

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Proprietary Name: Undetermined

Common or Usual Name: Ceramic Brackets

Classification Name: Bracket, Ceramic, Orthodontic

Classification Code: NJM

Identification of Legally Marketed Device: (Device Equivalence)

Proprietary Name: Transcend Ceramic Brackets

510K Number: K861965

Common or Usual Name: Ceramic Brackets

Classification Name: Bracket, Ceramic, Orthodontic

Classification Code: DYW

Device Manufacturer: 3M-Unitek Corp.

Proprietary Name:	Transcend Ceramic Brackets
510K Number:	K944286
Common or Usual Name:	Ceramic Brackets
Classification Name:	Bracket, Ceramic, Orthodontic
Classification Code:	DYW
Device Manufacturer:	3M-Unitek

Proprietary Name:	Clarity Modified Ceramic Brackets
510K Number:	K062305
Common or Usual Name:	Ceramic Brackets
Classification Name:	Bracket, Ceramic, Orthodontic
Classification Code:	NJM
Device Manufacturer:	3M-Unitek

Description of the Device:

The Ceramic Bracket line of products are single-use devices intended for use in conjunction with comprehensive orthodontics to control the movement of individual teeth.

These one-piece ceramic brackets are comprised of polycrystalline aluminum oxide. The general geometric composition of these devices is made of archwire slot, tie wings, and a pad (which provides a bonding surface). The archwire slot is a channel through the bracket used to engage the archwire. The tie wings are small hook shaped protrusion use as an anchor point for the ligature; ligatures work by tying the archwire into the archwire slot. The geometry of the pad is such that the bracket has a stable footprint. The pad is coated with aluminum oxide particles to facilitate bracket bonding with orthodontic adhesives.

These brackets are comprised of several geometries that vary from bracket to bracket, corresponding to the teeth they are intended for. These geometries contribute to the fit of the bracket to the tooth and also impart the axial control of the energy from the archwire.

Intended Use:

These devices are intended for the correction of orthodontic malocclusions as diagnosed by a dentist or orthodontist. They are used to transmit and provide axial directional control to the kinetic energy from an orthodontic archwire, for movement of individual teeth for treatment.

Summary of the technological characteristics of the device compared to the predicate devices:

The Ortho Organizer Ceramic Bracket System is substantially equivalent to the 3M Unitek Ceramic Bracket System. Table 1 summarizes the technological characteristics of this equivalence:

Table 1.

Product Parameter	Bracket	Predicate Product: 3M Unitek Transcend and Clarity*	Ortho Organizer's ceramic brackets	Substantial Equivalence Analysis
510k Number	All	K861965, K944286, K062305	Pending	N/A
Intended use per 872.5470	All	intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter the tooth's position	intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter the tooth's position	Equivalent
Bracket Body Material	All	99.9% Polycrystalline aluminum oxide	99.9% Polycrystalline aluminum oxide	Equivalent
Pad Coating Material	All	Irregular Microcyrstalline Aluminum Oxide	Irregular Microcyrstalline Aluminum Oxide	Equivalent
Biocompatibility	All	Yes	Yes	Equivalent
Single Use	All	Yes	Yes	Equivalent
Non-Sterile packaging	All	Yes	Yes	Equivalent
Color coded indicator for bracket identification	All	Yes	Yes, optional	Equivalent

* A claim of Substantial Equivalence to the 3M Unitek Ceramic Bracket system is not made for the metal insert feature available in this product line. The Transcend Bracket, like the Ortho Organizer Ceramic Bracket, does not include this feature.

Conclusion:

The Ortho Organizer Ceramic Bracket System has the same intended use and similar technological characteristics as the predicate device. The minor differences in technological characteristics do not raise new types of safety and effectiveness questions. Descriptive and performance testing demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 19 2011

Mr. Foster Boop
Director of Regulatory Affairs and Quality
Ortho Organizers, Incorporated
1822 Aston Avenue
Carlsbad, California 92008-7603

Re: K110335
Trade/Device Name: Ceramic Brackets Impression Compound
Regulation Number: 21 CFR 872.5470
Regulation Name: Plastic Orthodontic Bracket
Regulatory Class: II
Product Code: NJM
Dated: January 31, 2011
Received: February 15, 2011

Dear Mr. Boop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110335

Device Name: Ceramic Brackets

Indications for Use:

These ceramic brackets will be used for correction of malocclusions as diagnosed and overseen by trained practitioners of orthodontics. These brackets will be directly bonded to teeth; will have interface with the archwire to direct applied forces. These devices are intended for single use only and are not delivered in a sterile state.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110335